A Boon for the Diabetic

Among a representative selection of spinoffs to medicine is a space-derived pump that offers new freedom to people dependent on insulin

Diabetes mellitus is a disease wherein a malfunctioning pancreas fails to manufacture enough of the hormone insulin to keep the amount of sugar in the blood at a normal level. Poor control of blood sugar levels can cause such serious complications as blindness, kidney disease, nerve damage, loss of extremities, even death. To maintain blood sugar control, many diabetics—more than a million in the United States—need daily, twice daily or multiple injections of insulin. This generally provides the requisite control, but at a price: the insulin dependent diabetic is tied to a rigid schedule in which mealtimes, sleep time and exercise must be matched to insulin injections and "peaking."

Some 12,000 diabetics have freed themselves of such lifestyle restrictions through pump therapy. A development of recent years, pump therapy involves use of an external pump to deliver insulin continuously at a preprogrammed, individually adjusted rate. No longer concerned with scheduling activities around peaking insulin levels, the pump wearer can lead a more normal existence, even participate in sports or travel. And there is an even greater benefit: research indicates that infusion of "short-acting" insulin in tiny amounts over a long period—instead of multiple daily injections of "long-acting" insulin—has helped many diabetics achieve better control of blood sugar levels, thereby minimizing the possibility of complications and in some cases even halting the progression of complications.

An example of a pump system is the MiniMed® 504 Insulin Infusion Pump, a space spinoff manufactured by MiniMed Technologies, Sylmar, California. MiniMed 504 is designed to replicate, to the extent possible, the action of the pancreas in a normal person. Dimensionally no larger than a credit card, it weighs only 3.8 ounces, which is important to someone who must wear it 24 hours a day. Within that compact package, it houses a microprocessor, a long-life battery, and a syringe reservoir filled with insulin. The syringe is connected to an infusion set, which consists of a thin, flexible plastic tube about 30 inches long with a needle at its end. The patient inserts the needle subcutaneously, usually in the abdomen.

Clipped to a belt or just about any part of the wearer's clothing, the minipump infuses insulin in two ways: the "basal rate," a preprogrammed continuous delivery at the precise rate of one microliter per stroke; and the "bolus," a larger amount of insulin administered prior to meals or when blood sugar levels are elevated. The pump is not automatic; it must be told how much insulin to give and when to give it. The proper amount is determined by careful monitoring of the patient's blood sugar levels, taking into consideration the effects of stress, exercise, different kinds of food and other factors that influence blood sugar levels. The amount is communicated to MiniMed 504's microprocessor by tapping pushbuttons. The system can be programmed with up to four basal rates; this is important to patients whose insulin requirements change during the course of a day.

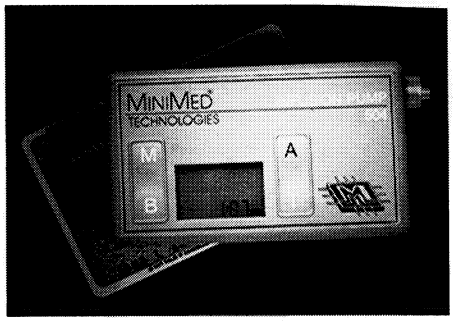
MiniMed 504 traces its ancestry to NASA-funded research in the 1970s which sought to transfer to the field of medical instrumentation space-derived microminiaturization techniques. A key player in the program was the Applied Physics Laboratory (APL) of Johns Hopkins University, whose extensive and innovative work in design of small satellites had provided a technology base for developing medical systems in which electronic and other components were

reduced to incredibly tiny dimensions.

One such system was the Programmable Implantable Medication System (PIMS), developed by APL in cooperation with Goddard Space Flight Center and Pacesetter Systems, a manufacturer of cardiac pacemakers located in Sylmar, California. In 1981, Pacesetter formed an Infusion Division, incorporating its research and development personnel who had worked on the NASA/APL program; the division continued work on an advanced version of PIMS and also initiated work on external insulin pumps, of which MiniMed 504 is a third generation product. In May 1985, when Pacesetter Systems was acquired by Siemens Corporation, the Infusion Division became a separate, privately-held company named MiniMed Technologies.

MiniMed continues to refine external pump technology and has developed the implantable insulin pump to the point where it is undergoing human clinical trials, initiated last year. The company's long-range goal is a commercially available artificial pancreas with a sensor that will continually measure blood sugar level and automatically regulate insulin delivery through an implanted pump. The "when" is uncertain, due to the extensive development and testing required to achieve the requisite reliability but the goal, says MiniMed, "appears more and more attainable." ▲

® MiniMed is a registered trademark of MiniMed Technologies.



At left, a MiniMed Technologies technician uses magnifying glasses to assemble the tiny parts of a MiniMed 504 Insulin Infusion Pump, an aid to diabetics shown in closeup above.

Above, a MiniMed 504 user (seated) is briefed on the operation of the system. Clipped to a patient's clothing (left), the minipump delivers insulin continuously at a preprogrammed rate adjusted to the individual, allowing the insulin-dependent diabetic to lead a more normal life.